UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

VICTORIA HILL,)	
)	
Plaintiff(s),)	
)	
VS.)	Case No. 4:03CV1526 JCH
)	
WYETH, INC.,)	
)	
Defendant(s).)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendant Wyeth, Inc.'s Motion for Partial Summary Judgment, filed January 16, 2007. (Doc. No. 45). The matter is fully briefed and ready for disposition.

BACKGROUND

On or about September 2, 2003, Ms. Victoria Hill¹ filed this action for damages in the Circuit Court of the City of St. Louis, Missouri. (Doc. No. 1-3, Petition for Damages (hereinafter "Complaint" or "Compl."). Ms. Hill alleged she was injured as a result of her use of the prescription diet drug dexfenfluramine, manufactured and distributed by Defendant Wyeth, Inc. ("Wyeth") under the brand-name "Redux".² (Compl., ¶¶ 14, 28). Ms. Hill's physician, Dr. Sherry Shuman, prescribed

¹ The sole remaining Plaintiff in this matter, Victoria Hill, passed away during the pendency of this matter. Ms. Hill's mother, Mable Gillespie, has been substituted as Plaintiff in this matter.

² At various points in their filings, the parties allege Ms. Hill ingested fenfluramine, distributed under the brand-name "Pondimin." Throughout her response to Wyeth's Motion for Partial Summary Judgment, however, Plaintiff maintains Ms. Hill used Redux, and the Court will assume that to be the case for purposes of this Memorandum and Order.

Redux for Ms. Hill in May, 1997.³ (Wyeth's Statement of Uncontroverted Material Facts ("Wyeth's Facts"), ¶ 7, citing Exh. C, Shuman Dep., P. 36). According to Plaintiff, Redux was pulled from the market in September, 1997, when it was conclusively linked to numerous reported cases of primary pulmonary hypertension, and valvular heart disease. (Plaintiff's Response to Defendant Wyeth's Motion for Partial Summary Judgment ("Plaintiff's Response"), P. 1). Wyeth removed the action to this Court on October 24, 2003. (Doc. No. 1).

In her Complaint, Plaintiff asserts five causes of action against Wyeth: Breach of Express and Implied Warranties (Count I); Strict Products Liability/Defective Design (Count II); Strict Products Liability/Failure to Warn (Count III); Negligence (Count IV); and Liability under Restatement (Second) of Torts, § 402(b).⁴ As stated above, Wyeth filed the instant Motion for Partial Summary Judgment on January 16, 2007.

SUMMARY JUDGMENT STANDARD

The Court may grant a motion for summary judgment if, "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Citrate, 477 U.S. 317, 322 (1986). The substantive law determines which facts are critical and which are irrelevant. Only disputes over facts that might affect the outcome will properly preclude summary judgment. Anderson v. Liberty Lobby, Inc., 477

 $^{^3}$ While taking Redux, Ms. Hill estimated she lost between 20 and 30 pounds. (Wyeth's Facts, \P 8).

⁴ Plaintiff's claim under § 402(b) may be found in her Severed and Amended Complaint, filed in the multidistrict litigation in this matter before Judge Harvey Bartle, III, of the United States District Court for the Eastern District of Pennsylvania. (Doc. No. 38-7).

U.S. 242, 248 (1986). Summary judgment is not proper if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Id.

A moving party always bears the burden of informing the Court of the basis of its motion. Celotex, 477 U.S. at 323. Once the moving party discharges this burden, the nonmoving party must set forth specific facts demonstrating that there is a dispute as to a genuine issue of material fact, not the "mere existence of some alleged factual dispute." Fed. R. Civ. P. 56(e); Anderson, 477 U.S. at 247. The nonmoving party may not rest upon mere allegations or denials of its pleadings. Anderson, 477 U.S. at 256.

In passing on a motion for summary judgment, the Court must view the facts in the light most favorable to the nonmoving party, and all justifiable inferences are to be drawn in its favor. Anderson, 477 U.S. at 255. The Court's function is not to weigh the evidence, but to determine whether there is a genuine issue for trial. <u>Id</u>. at 249.

DISCUSSION

I. Only Plaintiff's Claims Of Failure To Warn Should Survive Summary Judgment

In its first argument in favor of summary judgment, Wyeth asserts that because Plaintiff's claims are all premised on an alleged failure to warn Ms. Hill's prescribing physician of the risk of valvular heart disease associated with Redux, only Plaintiff's failure to warn claims should survive. (Wyeth's Suggestions in Support of Motion for Partial Summary Judgment ("Wyeth's Memo in Support"), PP. 4-6). In support of this assertion, Wyeth maintains courts in both the Eastern District of Texas and the Western District of Oklahoma have so held. (Id., citing In re Norplant Contraceptive Products Liability Litigation, 955 F.Supp. 700 (E.D. Tex. 1997), and Stafford v. Wyeth, 411 F.Supp.2d 1318 (W.D. Okla. 2006)).

Upon consideration, the Court will deny this portion of Wyeth's Motion for Partial Summary Judgment, for two reasons. First, the Court's review of Plaintiff's Complaint reveals she clearly intends to pursue claims unrelated to Wyeth's alleged failure to warn. For example, in Count I, Plaintiff alleges Wyeth breached its expressed and implied warranties that Redux was safe for its intended use, and free from manufacturing or production defects. (Compl., ¶¶ 49, 50). Further, in Count II, Plaintiff alleges Redux was defective in design and unreasonably dangerous. (Id., ¶¶ 54, 55). Finally, in Count IV, Plaintiff alleges Wyeth breached its duty of reasonable care by failing to, among other things, conduct sufficient testing of Redux. (Id., ¶ 68(a)). With these allegations, Plaintiff expresses concerns unrelated to Wyeth's alleged failure to warn of the risks associated with Redux.

As further support for its ruling, the Court finds both In re Norplant and Stafford distinguishable from the instant case. Specifically, the Court notes that in his Order in In re Norplant, Chief Judge Schell stated Plaintiffs' claims for breach of express warranty, breach of implied warranty of fitness for a particular purpose, manufacturing defect, design defect, negligent manufacture, and negligent design, some or all of which presumably did not rely on the defendants' alleged failure to warn, had all been dismissed as abandoned. See In re Norplant, 955 F.Supp. at 703 n. 7. Furthermore, the Court's review of the underlying record in Stafford reveals the plaintiff in that case did not contest the defendant's contention her claims all hinged on defendant's alleged failure to warn. As each of these circumstances differs significantly from those of the present case, this Court finds reliance on In re Norplant and Stafford to be inappropriate. This portion of Wyeth's Motion for Partial Summary Judgment will therefore be denied.

II. Plaintiff's Breach Of Warranty Claims Fail Because Plaintiff Cannot Show The Key Element Of Reliance

Wyeth next asserts Plaintiff's claims for breach of warranty fail, because Plaintiff presents no evidence Ms. Hill relied on any representation by Wyeth. (Wyeth's Memo in Support, P. 6). The Court agrees that Plaintiff's claims of breach of express and implied warranties require proof of reliance on a statement made by Wyeth. See Lachance v. American Home Products Corp., 2006 WL 89850 at *3 (W.D. Mo. Jan. 13, 2006) (citations omitted). Upon review of the record, the Court finds Plaintiff fails to allege this essential element. Rather, the Court notes that in her response, Plaintiff asserts Ms. Hill's medical providers relied on the statements and representations contained in the package insert for Redux. (Plaintiff's Response, P. 8). Plaintiff provides no evidence, however, that Ms. Hill herself, "read any material regarding the drug or side effects, read any advertising in making her decision to take the drug, or relied on any written or oral statements from Wyeth...in 'deciding' to 'buy' [Redux]." Lachance, 2006 WL 89850 at *3. Under these circumstances, summary judgment is appropriate on Plaintiff's claims of breach of express and implied warranties. Id.

III. The Learned Intermediary Doctrine Bars Plaintiff's Claims For Misrepresentation

Wyeth next asserts it is entitled to judgment as a matter of law on Plaintiff's misrepresentation claims, under the learned intermediary doctrine. (Wyeth's Memo in Support, PP. 7-8). The Eighth Circuit has explained the learned intermediary doctrine as follows:

As a general rule, the manufacturer of a product has a duty to warn the user of dangers inherent in that product under the theories of strict liability, negligence and breach of warranty, and the comment k defense. One of the exceptions to this general proposition is the learned intermediary rule, which assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects. There are several arguments supporting the application of this exception to prescription drug products. First, medical ethics and practice dictate that the doctor must be an intervening and independent party between patient and drug manufacturer. Second, the information regarding risks is often too technical for a patient to

make a reasonable choice. Third, it is virtually impossible in many cases for a manufacturer to directly warn each patient.

Hill v. Searle Laboratories, a Div. of Searle Pharmaceuticals, Inc., 884 F.2d 1064, 1070 (8th Cir. 1989) (footnote omitted). Wyeth notes that under the learned intermediary doctrine, Wyeth had only a duty to warn Plaintiff's prescribing physician of the adverse effects of Redux, not Plaintiff herself. (Wyeth's Memo in Support, P. 7; see also In re Diet Drugs Products Liability Litigation, 220 F.Supp.2d 414, 423 (E.D. Penn. 2002)). Wyeth thus asserts a claim it failed to warn Ms. Hill's physician is the only claim Plaintiff should be permitted to pursue. (Wyeth's Memo in Support, P. 8).

Upon review, the Court finds Plaintiff fails to counter Wyeth's argument regarding the learned intermediary doctrine. Rather, Plaintiff's response focuses on the alleged inadequacy of Wyeth's warning; nowhere does she assert Wyeth had a duty to warn Ms. Hill personally, rather than Ms. Hill's prescribing physician. (Plaintiff's Response, PP. 2-4). This portion of Wyeth's Motion for Partial Summary Judgment will therefore be granted.

IV. Comment K Prohibits Plaintiff's Strict Liability Claim

In its final argument in favor of summary judgment, Wyeth asserts that Comment k to the Restatement (Second) of Torts, § 402A, prohibits Plaintiff's strict liability claim. (Wyeth's Memo in Support, PP. 8-10). The Restatement (Second) of Torts, § 402A, states in relevant part as follows:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

⁵ Missouri courts adhere to the learned intermediary doctrine. <u>See Doe v. Alpha Therapeutic</u> Corp., 3 S.W.3d 404, 419 (Mo. App. 1999) (citations omitted).

Restatement (Second) of Torts, § 402A(1). Comment k provides an exception to this rule, however, stating in relevant part as follows:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs....Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs,...many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician....The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use,....

Restatement (Second) of Torts, § 402A Comment k. Wyeth asserts prescription medications like Redux are examples of products immune from strict liability claims under comment k. (Wyeth's Memo in Support, P. 9).

In <u>Hill v. Searle Laboratories</u>, the Eighth Circuit rejected the notion that comment k automatically shields all prescription drug products; rather, it, "limited the application of comment k to circumstances when it is shown that the product is incapable of being made safe given the present state of human knowledge but possess such a high degree of social need so that its use is warranted, provided warnings are adequate." <u>Hill v. Searle Laboratories</u>, 884 F.2d at 1068 (citations omitted). The Eighth Circuit concluded that, "whether a product is within the scope of comment k should be determined on a case-by-case basis." <u>Id.</u> at 1069 (footnote and citations omitted).

In <u>Lachance v. American Home Products Corporation</u>, a Court in the Western District of Missouri considered the application of comment K to Pondimin, and concluded that whether the diet drug at issue was unavoidably unsafe was a question of fact for the jury. <u>Lachance</u>, 2006 WL 89850 at *4. Upon consideration, the Court finds this reasoning equally applicable to Redux, and so this portion of Wyeth's Motion for Partial Summary Judgment will be denied.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendant Wyeth, Inc.'s Motion for Partial Summary Judgment (Doc. No. 45) is **GRANTED** in part and **DENIED** in part, in accordance with the foregoing.

Dated this 28th day of February, 2007.

/s/ Jean C. Hamilton

UNITED STATES DISTRICT JUDGE